



# UNITED STATES PATENT AND TRADEMARK OFFICE

M

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,964	10/12/2000	Geert Maertens	2551-48	5719
23117	7590	09/09/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/686,964	<b>Applicant(s)</b> MAERTENS ET AL.	
	<b>Examiner</b> Myron G. Hill	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 36- 49, 62- 110 is/are pending in the application.
- 4a) Of the above claim(s) 42, 43, 79, 89, 103, and 105- 107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36- 41, 44- 49, 62- 78, 80- 88, 90- 102, 104 and 108- 110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/14/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to paper filed 6/14/04.

#### ***Election/Restrictions***

Newly submitted claims 79, 89, 103, and 105- 107 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are drawn to methods of making a product (kit) and have different method steps for each variation of the method. The original claims were drawn to a product, not a method of making a product and the methods would have been subject to restriction because there are many methods to make the same product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 79, 89, 103, and 105- 110 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 36- 41, 44- 49, 62- 78, 80- 88, 90- 102, 104 and 108- 110 are under consideration.

#### ***Information Disclosure Statement***

The information disclosure statement filed 6/14/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copies were received with the IDS paper.

### **Rejections Maintained or Necessitated By Amendment**

#### ***Claim Rejections - 35 USC § 112***

Claims 44- 49 and new claims 83- 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to epitopes comprising at least one amino acid residue selected from the recited group of single amino acids.

Applicant argues that the specification discloses the recited residues on page 17 and these are isolate specific amino acids as well as amended the claims to recite epitopes of 5- 6 residues. Applicant argues that one of ordinary skill in the art would appreciate the description as exemplified. Lastly, the Examiner is urged to appreciate that the epitopes of the claims require more than one amino acid.

Applicant's arguments have been fully considered and not found persuasive.

The claims do not recite isolate specific amino acids and neither does the specification at page 17, lines 6- 10. There is merely a list of single amino acids and a list of combinations.

Applicant has not taught specific linear or conformational epitopes that comprise the recited residues, or what properties (specific sequences that antibodies bind to) these epitopes have over the many other epitopes in the NS3 polypeptide of HCV. Thus, it is concluded that applicant did not have in their possession the full range of epitopes claimed.

The rejection is maintained and applies to the new claims listed above.

### ***Claim Rejections - 35 USC § 103***

Claims 36- 38, 40, 41, and 62- 76, 81 87, 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al. (US 6036579) and Harlow and Lane.

The claims are drawn to an HCV NS3 immunoassay wherein sulphonation and desulphonation is added in at least one step.

Applicant argues that the method of sulphonation and desulphonation leads to a product with better activity and/or conformation closer to native protein than the products made by the prior art methods.

Applicant's arguments have been fully considered and not found persuasive.

The Office considers a "kit" claim to be a product. That product is what the kit contains/comprises.

It is noted that the claims have been amended to recite sulphonation and desulphonation as product by process steps. The product claimed now is desulphonated.

Applicant has not pointed out how the product is different than the cited prior art or is different from the previously claimed product.

Page 15 of the specification discloses that DTT is used to desulphonate the product. DTT is used in the prior art as cited in the rejection of record. Thus, the product of the prior art is desulphonated and is the same as the now claimed product.

The rejection of record is maintained for reasons above and as cited in the prior action and is also applied to the new claims.

Claims 39, 44- 49, 80, and 82- 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al. (US 6036579) and Harlow and Lane as applied to claims 36- 38, 40, 41, and 44- 76 above, and further in view of Leroux-Roels.

Applicant argues that the method of sulphonation and desulphonation leads to a product with better activity and/or conformation closer to native protein than the products made by the prior art methods.

Applicant's arguments have been fully considered and not found persuasive.

The basis of the rest of the rejection as stated in the previous rejection.

Applicant has not argued that the claimed sequence is taught by Leroux-Roels (SEQ ID# 2) is not the same as SEQ ID# 18.

The rejection is maintained and is also applied to the new claims.

Claims 77, 78, 104, and 108- 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al. (US 6036579) and Harlow and Lane as applied to claims 36- 38, 40, 41, and 44- 76 above, and further in view of Icardi *et al.*

Applicant argues that the method of sulphonation and desulphonation leads to a product with better activity and/or conformation closer to native protein than the products made by the prior art methods.

Applicant's arguments have been fully considered and not found persuasive.

The basis of the rejection is as stated in the previous two rejections.

Applicant has not pointed out how the product is different or how Icardi *et al.* do not make obvious the controls used in the claimed product.

The rejection of record is maintained for reasons above and as cited in the prior action and is also applied to the new claims.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within


Art Unit: 1648

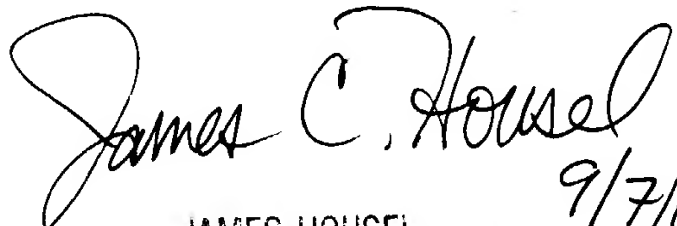
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
September 7, 2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
9/7/04